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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/064,682      04/22/98      PETERSEN      J      273802002200

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755 PAGE MILL ROAD  
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EXAMINER
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SWARTZ, R

ART UNIT	PAPER NUMBER
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1641

DATE MAILED:

05/09/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trad marks**

# Office Action Summary

Application No.  
09/064,682

Applicant(s)  
Petersen

Examiner  
Rodney P. Swartz, Ph.D.

Group Art Unit  
1641



☒ Responsive to communication(s) filed on 7 February 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-3 and 5-26 is/are pending in the application.

Of the above, claim(s) 21-26 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-3 and 5-20 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-3 and 5-26 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit:

### **DETAILED ACTION**

1. Applicant's Response to Office Action, received 7 February 2000, paper #11, is acknowledged. Claim 4 has been canceled. Claims 1, 6, 12, 19, and 20 have been amended.
2. Claims 1-3 and 5-26 are pending. Claims 21-26 are withdrawn from further consideration by the examiner, 37 CAR 1.142(b) as being drawn to a non-elected invention.
3. Currently, claims 1-3 and 5-20 are under consideration.

### **Rejection Moot/Withdrawn**

4. The rejection of claim 4 under 35 U.S.C. 112, first paragraph, scope of enablement is moot in light of the cancellation of claim 4.
5. The rejection of claim 4 under 35 U.S.C. 112, second paragraph, as being indefinite, is moot in light of the cancellation of claim 4.
6. The rejection of claim 4 under 35 U.S.C. 103(a) as being unpatentable over JP3109328 in view of Elson (*Current Topics in Microbiology*, 146:29-33, 1989) is moot in light of the cancellation of claim 4.
7. The rejection of claim 6 under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn in light of the amendment of claim 6 to recite "bystander antigen".

### **Rejections Maintained**

Art Unit:

8. The rejection of claims 1, 2, and 5-20 under 35 U.S.C. 112, first paragraph, scope of enablement is maintained.

Applicant argues that the properties of mucosal binding partners are discussed in the specification, but that in the interest of expediting prosecution, applicant has amended the instant claims to recite cholera toxin B peptide (CTB) or *E. coli* heat-labile enterotoxin B subunit (LTB) peptide. Applicant argues that examiner has admitted enablement of CTB. Applicant argues that LTB is also enabled in light of the disclosure (pages 17 and 18).

The examiner has considered applicant's arguments, and finds it persuasive concerning CTB, but does not find it persuasive concerning LTB. Pages 17 and 18 of the instant specification merely defines the term LTB and provides a reference for preparing recombinant LTB. The specification does not provide guidance for a person skilled in the art to substitute unconjugated LTB for CTB in the instant claims, especially in light of the history in the art wherein the only support for LTB has been when LTB has been linked to tolerogens.

9. The rejection of claims 1-3 and 5-20 under 35 U.S.C. 103(a) as being unpatentable over JP3109328 in view of Elson (*Current Topics in Microbiology*, 146:29-33, 1989) is

Applicant argues that the JP abstract teaches only that administration of CTB reduces transplant rejection when administered prior to transplantation, but does not teach or suggest any immune tolerization activity of CTB nor mucosal administration of CTB.

Applicant argues that Elson fails to cure the deficiencies of the JP abstract, because a failure to elicit an immune response neither teaches nor suggests anything about tolerization.

Art Unit:

The examiner has considered applicant's arguments, but does not find them persuasive for reasons of record. In addition, the instant claims are drawn to a method comprising administering to a mucosal surface a composition comprising an inducing agent and a mucosal binding component.

The abstract of Japanese document JP3109328 supplied by applicant teaches that cholera toxin B subunit administered prior to administration of bone marrow cells results in prevention of transplant of the bone marrow. Therefore, the abstract teaches that an immune response which would normally result from such a heterologous bone marrow transplant is abrogated by the administration of unconjugated CTB. In the absence of evidence to the contrary, the abrogation is tolerance.

The Elson reference has been provided for administration route of CTB, i.e., mucosal. Therefore, in the absence of evidence to the contrary, it would have been obvious to administer the CTB which abrogates the bone marrow cell transplant taught by JP3109328 by the mucosal route taught by Elson.

### **New Rejections**

#### **Claim Rejections - 35 USC § 102**

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

Art Unit:

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

11. Claim 12, 13, 14, are rejected under 35 U.S.C. 102(e) as being anticipated by Holmgren et al (U.S. Pat. No. 5,681,571).

The instant claims are drawn to a method of inducing immunological tolerance to a mucosal antigen comprising administering to a mucosal surface a composition comprising a mucosal binding component. The instant claims do not recite any limitations concerning the relationship of the mucosal binding component and the mucosal antigen.

Holmgren et al teach a method of inducing immunological tolerance to mucosal antigen comprising administering to a mucosal surface a composition comprising a mucosal binding component (Abstract; col. 8, line 61 to col. 24, line 10).


### **Conclusion**

12. No claims are allowed.
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703)308-4027. The facsimile telephone number for the Art Unit Group is (703)308-4242.

Art Unit:

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.

  
**RODNEY P. SWARTZ, PH.D**  
**PATENT EXAMINER**

Art Unit 1641

May 8, 2000